IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED,	)	
	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Millennium Pharmaceuticals, Inc., by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et seq. as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendant Sun Pharmaceutical Industries Limited ("Sun"). This action arises out of the submission by Sun of Abbreviated New Drug Application ("ANDA") No. 214125 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NINLARO® ("the Sun ANDA Product") prior to the expiration of U.S. Patent Nos. 7,442,830; 8,859,504; and 9,175,017 (the "Patents-in-Suit").

PARTIES

2. Plaintiff Millennium Pharmaceuticals, Inc. ("Millennium") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts 02139. Millennium is engaged in the business of developing, manufacturing, and selling pharmaceutical drug products, particularly for use in the therapeutic area of oncology.

3. Upon information and belief, Sun is a corporation organized and existing under the laws of the Republic of India, with its principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

4. Upon information and belief, Sun, itself and through its subsidiaries and agents, manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in Delaware.

5. Upon information and belief, following any FDA approval of ANDA No. 214125, Sun, itself and through its subsidiaries and agents, will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 214125 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America 35 U.S.C. §§ 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. The Court has personal jurisdiction over Sun because, among other things, Sun has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Millennium, a Delaware corporation. For example, on information and belief, following approval of ANDA No. 214125, Sun intends to make, use, import, sell, and/or offer for sale the Sun ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

8. This Court also has personal jurisdiction over Sun because, among other things, this action arises from actions of Sun directed toward Delaware, and because Sun has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Sun derives substantial revenue from the sale of pharmaceutical products that are sold, used, and/or consumed within Delaware and has availed itself of the privilege of conducting business within Delaware.

9. Sun has taken advantage of the jurisdiction of this Court by filing claims and counterclaims in this Court and/or consenting to personal jurisdiction, including in, e.g., *Pfizer Inc. et al v. Sun Pharmaceutical Industries, Ltd. et al.*, C.A. No. 19-758 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, C.A. No. 18-1765 (D. Del.); *Novartis Pharmaceuticals Corporation v. Sun Pharmaceutical Industries, Ltd., et al.*, C.A. No. 18-1040 (D. Del.); and *Sun Pharmaceutical Industries Ltd. et al. v. Saptalis Pharmaceuticals, LLC*, C.A. No. 18-648 (D. Del.).

10. In the alternative, this Court may exercise personal jurisdiction over Sun because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391(c) because, upon information and belief, Sun is not resident in the United States and may thus be sued in any judicial district.

BACKGROUND

12. United States Patent No. 7,442,830 ("the '830 patent"), entitled "Proteasome Inhibitors" (Exhibit A hereto), was duly and legally issued on October 28, 2008. The '830 patent, which is owned by Millennium, will expire on November 20, 2029.

13. United States Patent No. 8,859,504 ("the '504 patent"), entitled "Boronate Ester Compounds and Pharmaceutical Compositions Thereof" (Exhibit B hereto), was duly and legally issued on October 14, 2014. The '504 patent, which is owned by Millennium, will expire on June 16, 2029.

14. United States Patent No. 9,175,017 ("the '017 patent"), entitled "Boronate Ester Compounds and Pharmaceutical Compositions Thereof" (Exhibit C hereto), was duly and legally issued on November 3, 2015. The '017 patent, which is owned by Millennium, will expire on June 16, 2029.

15. NINLARO® is a proteasome inhibitor approved by the FDA for oral administration in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

16. Millennium sells NINLARO® in the United States pursuant to New Drug Application No. 208462, which was approved by the FDA in 2015.

17. NINLARO®, and its use, are covered by one or more claims of the Patents-in-Suit, which have been listed in connection with NINLARO® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

18. By letter dated January 16, 2020 (the "Notice Letter"), Sun notified Millennium that it had submitted to the FDA ANDA No. 214125 for ixazomib citrate capsule, EQ. 2.3 mg

base, EQ. 3 mg base, and EQ. 4 mg base, a generic version of NINLARO® ("the Sun ANDA Product").

19. By submitting ANDA No. 214125, Sun has necessarily represented to the FDA that the Sun ANDA Product has the same active ingredient as NINLARO®, has the same dosage forms and strengths as NINLARO®, and is bioequivalent to NINLARO®.

20. In the Notice Letter, Sun stated that its ANDA included Paragraph IV certifications pursuant to 21 U.S.C. § 355(j) with respect to the Patents-in-Suit and alleged that the Patents-in-Suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Sun ANDA Product. The Notice Letter also informed Millennium that Sun seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Sun ANDA Product before the Patents-in-Suit expire.

21. Upon information and belief, Sun had knowledge of the Patents-in-Suit when it submitted ANDA No. 214125 to the FDA.

22. Upon information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 214125.

23. This action was commenced before the expiration of forty-five days from the date of Millennium's receipt of the January 16, 2020 Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 7,442,830

24. Millennium incorporates each of the preceding paragraphs 1-23 as if fully set forth herein.

25. Sun's Notice Letter did not contest infringement of claims 1, 2, 4, 5, and 8 of the '830 patent except on the basis of their assertion that these claims are invalid.

26. Sun's submission of ANDA No. 214125 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '830 patent was an act of infringement of at least claims 1, 2, 4, 5, and 8 of the '830 patent ("the '830 Asserted Claims") under 35 U.S.C. § 271(e)(2)(A).

27. Sun's commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to the expiration of the '830 patent, and Sun's inducement of and/or contribution to such conduct, would further infringe at least the '830 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

28. Upon FDA approval of ANDA No. 214125, Sun will infringe at least the '830 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '830 patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Sun has notified Millennium of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA product before the expiration of the '830 patent.

29. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '830 patent.

30. Pursuant to 28 U.S.C. § 2201, Millennium is entitled to a declaratory judgment that Sun's making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe at least the '830 Asserted Claims pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

31. Upon information and belief, Sun acted, and upon FDA approval of ANDA No. 214125, will act, without a reasonable basis for believing that it would not be liable for infringing the '830 patent. This is an exceptional case.

32. Unless Sun is enjoined from infringing the '830 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 8,859,504

33. Millennium incorporates each of the preceding paragraphs 1-32 as if fully set forth herein.

34. Sun's Notice Letter did not contest infringement of claims 1, 2, and 15 of the '504 patent except on the basis of their assertion that these claims are invalid.

35. Sun's submission of ANDA No. 214125 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '504 patent was an act of infringement of at least claims 1, 2 and 15 of the '504 patent ("the '504 Asserted Claims") under 35 U.S.C. § 271(e)(2)(A).

36. The commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product prior to the expiration of the '504 patent, and Sun's inducement of and/or contribution to such conduct, would further infringe at least the '504 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

37. Upon FDA approval of ANDA No. 214125, Sun will infringe at least the '504 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product, and/or by actively inducing and contributing to infringement of the '504 patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things,

Sun has notified Millennium of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA product before the expiration of the '504 patent.

38. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '504 patent.

39. Pursuant to 28 U.S.C. § 2201, Millennium is entitled to a declaratory judgment that Sun's making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe at least the '504 Asserted Claims pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

40. Upon information and belief, Sun acted, and upon FDA approval of ANDA No. 214125, will act, without a reasonable basis for believing that it would not be liable for infringing the '504 patent. This is an exceptional case.

41. Unless Sun is enjoined from infringing the '504 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 9,175,017

42. Millennium incorporates each of the preceding paragraphs 1-41 as if fully set forth herein.

43. Sun's Notice Letter did not contest infringement of claims 1, 2, 6, 7, 9-11, and 13 of the '017 patent except on the basis of their assertion that these claims are invalid.

44. Sun's submission of ANDA No. 214125 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '017 patent was an act of infringement of at least claims 1, 2, 6, 7, 9-11, and 13 of the '017 patent ("the '017 Asserted Claims") under 35 U.S.C. § 271(e)(2)(A).

45. The commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product prior to the expiration of the '017 patent, and Sun's inducement of and/or contribution to such conduct, would further infringe at least the '017 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon FDA approval of ANDA No. 214125, Sun will infringe at least the '017 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product, and/or by actively inducing and contributing to infringement of the '017 patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Sun has notified Millennium of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA product before the expiration of the '017 patent.

47. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '017 patent.

48. Pursuant to 28 U.S.C. § 2201, Millennium is entitled to a declaratory judgment that Sun's making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe at least the '017 Asserted Claims pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

49. Upon information and belief, Sun acted, and upon FDA approval of ANDA No. 214125, will act, without a reasonable basis for believing that it would not be liable for infringing the '017 patent. This is an exceptional case.

50. Unless Sun is enjoined from infringing the '017 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Millennium prays that this Court grant the following relief:

(a) A judgment that at least the Asserted Claims of the Patents-in-Suit are not invalid, are not unenforceable, and were infringed by Sun's submission of ANDA No. 214125 under 35 U.S.C. § 271(e)(2)(A), and that Sun's manufacture, use, offer to sell, sale, or importation of the Sun ANDA Product and/or its active ingredient prior to the expiration of all of the Patents-in-Suit, will infringe at least the Asserted Claims of the Patents-in-Suit, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a), (b), and/or (c);

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sun's ANDA No. 214125, or any product or compound that infringes the Patents-in-Suit, shall not be earlier than the expiration date of the last to expire of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Millennium is or becomes entitled;

(c) A declaratory judgment that Sun's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Sun ANDA Product and/or its active ingredient prior to the expiration of the Patents-in-Suit, would infringe at least the Asserted Claims of the Patents-in-Suit, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a), (b), and/or (c);

(d) An Order permanently enjoining Sun, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, and those acting in privity or concert with them, from making, having made, using, offering to sell, selling, marketing, distributing, or importing the Sun ANDA Product, its active ingredient, or any other product or compound that infringes the Patents-in-Suit, until after the expiration of the last to expire of the Patents-in-Suit,

including any extensions and/or additional periods of exclusivity to which Millennium is or becomes entitled;

(e) Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Millennium if Sun engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Sun ANDA Product or its active ingredient prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Millennium is or becomes entitled;

(f) A declaration that this is an exceptional case and an award of attorneys' fees to Millennium pursuant to 35 U.S.C. §§ 285 and 271(e)(4), together with its reasonable costs; and

(g) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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